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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/218,435	12/17/98	EDWARDS J	GENSET.019A

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HM22/0131

EXAMINER	
BUGAISKY,G	

ART UNIT	PAPER NUMBER
1653	10

DATE MAILED: 01/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/215,435	Dumas Milnes Edwards et al.
Examiner	**Group Art Unit**
Gabriele E. Bugaisky	1653

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-20 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-20 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 13-14, 16 and 18-19, drawn to a polynucleotide, recombinant vectors, host cells and compositions comprising the polynucleotide, method of using the transformed cells to produce a human polypeptide, classified in class 435, subclasses 69.1, 252.3, 320.1, and 325, and class 536/23.5 and 24.3.

II. Claims 9-12 and 15, drawn to a human polypeptide, classified in class 530, subclass 350.

III. Claims 17 and 20, drawn to an antibody against the polypeptide of Group III, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product as claimed can be made by chemical synthesis, such as by the Merrifield method or by purification from natural sources by methods such as ion exchange chromatography, immunoaffinity, ultrafiltration, reverse-phase HPLC, etc.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP §806.05 for inventive groups that are directed to different products, restriction is deemed to e proper because these products constitute apparently distinct inventions for the following reasons: the polynucleotides of group I, the proteins of group II and the antibodies of Group III are chemically distinct products unrelated in sequence and separately classified having separate fields of search. Other than the fact that the polypeptides and polynucleotides are derived from the same cell type, the polynucleotides of Group I have no relationship to the polypeptides of Group II and antibodies of Group III. The function and existence of either DNA or protein is not dependent on the existence of the other. The products of each Group (I, II or III) can be independently synthesized by chemical means. An antibody is encoded by an entirely different DNA than that the protein which is bound by that antibody, and the primary sequence of the antibody bears no relationship to the sequence of the detected protein. Each product has separate, unrelated uses and none are disclosed as being capable of use together. Further, it would place an undue burden on the examiner to examine several independent inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the search for one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

The claims of Group I are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than ten individual,

independent, and distinct nucleotide sequences in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996).

Applicant is required to select no more than ten of the individual sequences for examination. The search of the no more than ten selected sequences may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (*e.g.,* oligomeric probes and/or primers). Note that any claim which is amended or newly presented and recites specific cell clone, should recite both the clone number and the corresponding SEQ ID NO.

Groups II and III are each drawn to a polypeptide selected from a group of over 230 sequences and antibody raised against the polypeptide, respectively. This constitutes recitation of an implied, misjoined Markush group that contains multiple, independent and distinct inventions. Each of the different polypeptides is independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. §121.

Upon election of Group III or IV, Applicant is additionally required to elect a single polypeptide. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptides recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 7:30 AM to 4:00 PM on weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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January 19, 2000